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| EXAMINER | |
|---|---|
| MONTANO, MELISSA ANN | |

| ART UNIT | PAPER NUMBER |
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| 3738 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/561,878 | LUGINBUEHL, RETO | |
| | Examiner | Art Unit | |
| | MELISSA MONTANO | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/581,270.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

1. Claims 2, 6, 7, 12, and 24 are objected to because of the following informalities: Claim 2 recites “50, preferably more than 90%”, which the examiner suggests should read **-- 50%, preferably more than 90% --**, for purposes of clarity. Claim 6 recites "0,1 to 99,9%", which the examiner suggests should read **-- 0.1% to 99.9% --**, for purposes of clarity. Claim 7 recites “20,0 to 99,0%”, which the examiner suggests should read **-- 20.0% to 99.0% --**, for purposes of clarity. Claim 12 recites “calciumphosphate containing”, which appears to include a spelling and grammatical errors. The examiner suggests that the phrase should read **-- calcium phosphate contains --**. Claim 24 recites "said components are", which appears to be referring to the “externally added component” of claim 23. The examiner suggests that the phrase “said components are” should read **-- said component is --**. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 2 recites the phrase “said fibers are aligned to more than 50, preferably more than 90%”. It is not clear which portion of the prosthetic device the fibers are aligned to. Also, the examiner is unsure whether the limitation means that the fibers

cover 50, preferably more than 90% of the area they are aligned to. The examiner encourages applicant to provide further explanation regarding this issue.

5. Claim 22 recites the limitation "the layer system" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,626,950 B2 to Brown et al. (Brown).

Regarding at least claims 1, 2, 19, 21, 30, and 31

Brown teaches a prosthetic implant having a tissue scaffold component and a fixation component that is useful in the repair/regeneration of defects present at junction sites such as articular or meniscal cartilage (col. 3, lines 13-30). The scaffold component (prosthetic device; 20) has a polymeric phase (fiber layer; 22) and ceramic phase (base component; 24), which are mechanically interlocked at interphase region (stabilization area/cell barrier layer; 26). Each of the polymeric phase (fiber layer; 22), ceramic phase (base component; 24), and interphase region (stabilization area/cell barrier layer; 26) have pores (23, 25, and 27) with an open cell structure (col. 4, lines 28-34). Brown also depicts the interphase region (stabilization area; 26) as a zone comprising at least one layer, as claimed by applicant (fig. 1).

Though Brown does not explicitly teach that the fibers are aligned to more than 50, preferably more than 90%, essentially in parallel to the insertion axis, or essentially perpendicular to a top surface of the base component, the examiner asserts that it would have been obvious to try this type of orientation of fibers, particularly in view of the lack of any disclosed criticality of the claimed limitations (see page 6 of applicant's specification that states that fibers may change alignment direction). Further, claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit the claim to a particular structure. See MPEP 2111.04.

Regarding at least claims 3-8

The polymeric phase (fiber layer; 22), taught by Brown, may be either a natural or synthetic polymer, or combinations thereof. Natural biopolymers include collagen, elastin, etc. (col. 6, lines 61-65). Brown also teaches a variety of porosities ranging from about 20% to about 98% for the polymer foam (col. 4, lines 6-7), and more specifically, a porosity in the polymeric phase (fiber layer; 22) of about 80 to about 95% (col. 12, lines 19-22). The examiner asserts that this would necessarily constitute fibers having a liquid absorbing capacity in a range of 0.1 to 99.0%, as well as in a range of 20.0 to 99.0%, as claimed by applicant. The examiner also asserts that it would have been obvious to one having ordinary skill in the art to include that the liquid being absorbed by the fibers is an aqueous solution and/or body fluids, as claimed by applicant.

Though Brown does not explicitly teach a fiber diameter in the range of 50 nm to 1 mm or 1 μm to 250 μm, the examiner asserts that it would have been obvious to one

having ordinary skill in the art at the time of the invention to modify the scaffold of Brown to include these limitations in order to provide a prosthetic implant that would properly fit the size of defect in need of repair, particularly in view of the lack of any disclosed criticality (see page 8 of applicant's specification). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding at least claims 9-16

Brown teaches that the ceramic phase (base component; 24) lies adjacent to bone tissue (col. 12, lines 10-11) and may be composed of hydroxyapatite, calcium sulfates, calcium carbonates, magnesium calcium phosphates, and mixtures thereof, or of a porous polymer matrix with inclusions of short ceramic fibers (col. 6, lines 43-56). The examiner asserts that the materials taught by Brown necessarily constitute a bone substitute material and, since Brown contemplates mixtures of the materials, it would be obvious to use a composite material comprising at least a polymer component and a mineral phase, as claimed by applicant. Brown also teaches that the pores (25) in the ceramic phase (base component; 24) are interconnected and that the shape of the ceramic phase (base component; 24) is round, cylindrical, or conical (figure 1).

Regarding at least claims 17-18 and 20

Brown does not explicitly teach the diameter of the ceramic phase (base component; 24) ranging between 2 and 30 mm or 4 and 20 mm, or the height of the ceramic phase (base component; 24) ranging between 1 to 30 mm or 1 to 6 mm. Brown

also does not explicitly teach the thickness of the interphase region (stabilization area; 26) of 1 nm to 1 mm.

However, the examiner asserts that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the scaffold of Brown to include these limitations in order to provide a prosthetic implant that would properly fit the size of defect in need of repair, particularly in view of the lack of any disclosed criticality (see pages 10 and 13 of applicant's specification). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding at least claims 22-27 and 29

According to Brown, therapeutic agents (externally added component/pharmaceutical compound) may also be delivered via the implant (col. 10, lines 40-41). The examiner asserts that these therapeutic agents would necessarily constitute a chemical substance, particularly in view of the lack of criticality of this limitation in applicant's specification. The therapeutic agents taught by Brown include antibiotics and growth factors. Brown also teaches that cells including osteoblasts, chondrocytes, autogeneous, allogenic, and xenogenic, may be applied or seeded into the scaffold (prosthetic device; 20).

Regarding at least claims 28, 32, and 33

Brown teaches that the interconnecting pores of the device facilitate the transport of nutrients and/or invasion of cells into the scaffold, facilitating the ingrowth of tissue

and more closely mimicking naturally occurring tissue junctions (col. 3, lines 55-58). The examiner asserts that it would be obvious to one having ordinary skill in the art at the time of the invention that blood or any fraction thereof would be present throughout the scaffold, and particularly in the ceramic phase (base component; 24), as claimed by applicant. Brown also teaches that the fabrication of the scaffold having multiple layers each having its own characteristics of composition, porosity, strength, etc. permits the repair and regeneration of articular cartilage (col. 11, lines 52-65).

The examiner notes the use of functional language in the claims (see claims 32 and 33). It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The reference US Patent Application Publication No. 2003/0075822 A1 to Sivka et al. discloses a fiber-reinforced, polymeric implant material useful for tissue engineering, and method of making same are provided. The fibers are preferably aligned predominantly parallel to each other, but may also be aligned in a single plane. The implant material comprises a polymeric matrix, preferably a biodegradable matrix, having fibers substantially uniformly distributed therein. In preferred embodiments,

porous tissue scaffolds are provided which facilitate regeneration of load-bearing tissues such as articular cartilage and bone.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA MONTANO whose telephone number is (571)270-5785. The examiner can normally be reached on Monday-Friday 8:00AM-5:00PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

/Bruce E Snow/
Primary Examiner, Art Unit 3738